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BIOMET
CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Tracy J. Bickel
(574) 267-6639

Proprietary Name: Radiolucent Colles Compression/Distraction Bar

Common Name: External Fixator

Classification Name: Pin, Fixation, Threaded (888.3040)

Substantially Equivalent Devices: Biomet® Radiolucent Colles Fracture Kit (K001760)

Device Description: A carbon fiber rod has an aluminum cap threaded onto one end. That cap slides axially in another bar that is partially externally threaded. There is a slot that runs the length of the external thread that accepts a pin that is part of the aluminum cap. There are two circular nuts that tighten on the pin which allow the device to be used in either compression or distraction mode. The partially threaded rod is made of aluminum and the circular nuts of made of stainless steel.

Intended Use: Stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM Rodding, casting, and other means of internal fixation.

Summary of Technologies: The device's technological characteristics (materials, design, sizing, and indications) are similar to or identical to the predicate device.

Non-Clinical Testing: The following tests were used to determine substantial equivalence: Cantilever Testing, Torsional Testing, and Sawbone Lab Testing.

Clinical Testing: None provided as a basis for substantial equivalence.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

000046

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2002

Ms. Tracy J. Bickel
Regulatory Specialist
Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587

Re: K021182
Trade/Device Name: Radiolucent Colles Compression/Distraction Bar
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDW
Dated: April 11, 2002
Received: April 15, 2002

Dear Ms. Bickel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice Ms. Tracy J. Bickel requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021182
Device Name: ***Radiolucent Colles Compression/Distraction Bar***
Indications for Use:

Stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM Rodding, casting, and other means of internal fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021182